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Supplemental to the Preliminary Regulatory Impact Analysis of Proposed Regulations for Nutrition Labeling of Meat and Poultry Products; Proposed Rule

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317, 320, and 381

[Docket No. 91-006P]

RIN 0583-AB34

Supplemental to the Preliminary Regulatory Impact Analysis of Proposed Regulations for Nutrition Labeling of Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule; supplement to the preliminary regulatory impact analysis.

SUMMARY: This document gives notice and seeks comments on the Supplemental to the Preliminary Regulatory Impact Analysis of Proposed Regulations for Nutrition Labeling of Meat and Poultry Products. On November 27, 1991, the Food Safety and Inspection Service (FSIS) published a proposed rulemaking docket entitled, "Nutrition Labeling of Meat and Poultry Products" (56 FR 60302-60364). In that proposed rule, there was an appendix to the preamble which provided a Preliminary Regulatory Impact Analysis (PRIA). That preliminary analysis stated that the Agency would publish a supplement to the PRIA.

DATES: Comments must be received by February 25, 1992.

ADDRESSES: Written comments to: Policy Office, ATTN: Linda Carey, FSIS Hearing Clerk, room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Oral comments as provided by the Poultry Products Inspection Act should be directed to Mr. Charles Edwards at (202) 205-0080. (See also "Comments" under "SUPPLEMENTARY INFORMATION.")

FOR FURTHER INFORMATION CONTACT: Mr. Charles Edwards, Director, Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 205-0080.

SUPPLEMENTARY INFORMATION:

Comments

Interested persons are invited to submit written comments concerning this Supplemental to the Preliminary Regulatory Impact Analysis of Proposed Regulations for Nutrition Labeling of Meat and Poultry Products.

Written comments should be sent to the Policy Office at the address shown above and should refer to Docket Number 91-006N. Any person desiring an opportunity for an oral presentation of views as provided by the Poultry Products Inspection Act should make such request to Mr. Edwards so that arrangements can be made for such views to be presented. A transcript will be available for public inspection in the Policy Office from 9 a.m. to 12:30 p.m., and from 1:30 p.m. to 4 p.m., Monday through Friday.

Background

On November 27, 1991, the Food Safety and Inspection Service (FSIS) published a proposed rulemaking docket entitled, "Nutrition Labeling of Meat and Poultry Products" (56 FR 60302-60364). In that proposed rule, there was an appendix to the preamble which provided a Preliminary Regulatory Impact Analysis (PRIA). That preliminary analysis stated that the Agency would publish a supplement to the PRIA. The attached Supplemental to the Preliminary Regulatory Impact Analysis of Proposed Regulations for Nutrition Labeling of Meat and Poultry Products expands the PRIA by taking into consideration additional information provided during the comment period and developed by FSIS. The issues analyzed are: (a) The participation rates to be expected under a voluntary option, taking into consideration changed requirements on laboratory testing for the nutrient content of products and also taking into consideration the possibility of replacing laboratory analysis with recipe analysis, (b) the value of voluntary nutrition labeling by manufacturers as a signal of product quality to consumers, and (c) the costs of prior label approval.

Dated: February 4, 1992.

Ronald J. Prucha,

Acting Administrator.

Supplemental to the Preliminary Regulatory Impact Analysis of Proposed Regulations for Nutrition Labeling of Meat and Poultry Products

I. Introduction

This supplemental to the preliminary regulatory impact analysis (PRIA) published November 27, 1991 (FR 56, No. 229, 60349) expands the PRIA by taking into consideration additional information provided during the comment period and developed by the Food Safety and Inspection Service (FSIS). The following issues are analyzed: (A) The participation rates to be expected under a voluntary option, taking into consideration changed requirements on laboratory testing for the nutrient content of products and also taking into consideration the possibility of replacing laboratory analysis with recipe analysis, (B) the value of voluntary nutrition labeling by manufacturers as a signal of product quality to consumers, and (C) the costs of prior label approval.

A. Participation Under Voluntary Labeling

To evaluate the participation rates under a voluntary program, FSIS focused on the costs of laboratory testing because fewer tests per product should be necessary under the proposed rule than under current procedures. FSIS examined a sample of labels submitted for approval late in 1991. Two-thirds of the labels currently submitted use an abbreviated label format, listing fewer nutrients than required by the longer version that is proposed. For those manufacturers now using an abbreviated label, the cost of testing for additional nutrients offsets the fewer number of tests per product under the proposed regulations. For a manufacturer considering entering the labeling program voluntarily, the cost of the current abbreviated label and the proposed longer, FDA-consistent label would be about the same. Thus, the reduced number of laboratory tests under the proposed rule probably would not have a significant effect on participation under a voluntary labeling program.

With respect to recipe analysis, which is comparison of ingredients in a product with a data base listing nutrient content of the ingredients, it is clear that costs would be considerably reduced compared with laboratory testing. USDA is continuing to review the potential for supporting nutrition labels with recipe analysis. The key question is the reliability of the procedure, and the resultant public health risk, rather than the cost. FSIS proposes to use laboratory testing to determine whether labels are consistent with the nutrient content of foods. Maintaining consistency with FDA's standards of compliance would require a 95 percent probability that products contain at least 80 percent of some nutrients and not more than 120 percent of others. It is uncertain whether recipe analysis can assure manufacturers of meeting these compliance standards. However, if data bases are constructed using multiple tests of nutrients and entries meet FDA compliance standards, recipe analysis might be feasible. USDA invites comments on these questions and will continue to consider recipe analysis.

B. The Value of Voluntary Nutrition Labeling as a Signal of Product Quality to Consumers

The issue analyzed is whether the existence of a nutrition label provides consumers with a signal of product quality, apart from the specific information on the label. USDA considered three questions with respect to this issue: (1) Are labeled versions of a product lower in nutrients—such as fat, calories, cholesterol, and sodium—that the consumers may want to avoid? (2) If so, are consumers aware of this difference, and is this signal likely to be useful to a high-risk population? (3) Is the signal likely to be useful to the rest of the population? USDA reviewed available research and surveys bearing on these questions and found that the evidence indicates: (1) Although there is some uncertainty whether labeled versions of products are lower in nutrients consumers want to avoid, consumers seem to believe labeled versions are "better," (2) The lower-income, less-educated "high-risk" population is unlikely to benefit from this signal, and (3) The average consumer is also unlikely to benefit from this signal. Lack of motivation prevents high-risk consumers from benefiting. Survey data indicate that 44 percent of consumers always read labels the first time they purchase a product; another 37 percent of consumers sometimes read labels. These purchases are heavily influenced by nutrition information. Twelve percent of consumers rarely read labels and only 7 percent of consumers never read labels when first purchasing a product. Presumably, consumers who rarely or never read labels the first time they purchase products and are influenced by nutrition information would be the beneficiaries of the signal under voluntary labeling. They are estimated to be less than 10 percent of the population.

C. Prior Label Approval

The cost of prior label approval consists of the costs of applying for label approval, administrative costs, and costs of delays while products cannot be produced until labels are approved. Approximately 85 percent of labels are handled by expediters. Administrative costs were incorporated in the estimates that were included in the preliminary analysis. Some additional trade association data is supplied.

The costs of prior label approval are attributable to the proposed nutrition labeling rule only to the extent that the proposal would increase the number of label applications. This analysis considers the cost of prior labor approval as a separate issue, but one which could be combined with the proposed rule. The issue would exist even if the rule had not been proposed and USDA is considering alternative methods of improving the labeling process.

Trade association data indicates that the time from the decision to market a new or modified product until actual market placement averages over 28 weeks for FSIS-regulated processed foods, but only 18 weeks for FDA-regulated processed foods. If total consumer expenditures on processed meat and poultry remain the same, delays redistribute revenues among firms. This creates a market inefficiency because market shares are not as closely aligned with consumer demand as they could be. Therefore, FSIS invites further comments on all aspects of prior label approval, but particularly on the costs of delay to individual manufacturers.

II. The Value of Voluntary Nutrition Labeling as a Signal of Product Quality to Consumers

It has been suggested that consumers may use the mere presence of a nutrition label as a signal of "quality" when determining which brand of a product to purchase. Because much research has found that consumers use labels largely to limit consumption of such nutrients as fat, calories, cholesterol, and sodium, "quality" would mean that labeled brands would contain less of these nutrients than unlabeled brands.

There is some concern that if all products were to contain nutrition labels, this signaling effect might be lost. There is further concern that this loss might be particularly important for low-income, less-educated consumers, considered high-risk because they have higher rates of disease and death than the general population.

These hypotheses and concerns lead to several questions: (1) Are labeled versions of a product lower in nutrients consumers want to avoid? (2) If so, are consumers aware of this difference, and is this signal likely to be useful to a high-risk population? (3) Is the signal likely to be useful to the rest of the population?

At the moment, it is not known whether labeled versions of a product are lower in nutrients consumers want to avoid. Public Voice recently surveyed meat and poultry products in 10 supermarkets in the Washington, DC area, and concluded that products lower in fat were more likely to have a nutrition label (Morris, 1991). However, there are some problems with this conclusion. First, although it may be true within narrow product definitions, the conclusion does not hold across product classes. For example, 90% of poultry and turkey franks were found to have nutrition labels, compared to only 30% of beef hot dogs. But among frozen multi-serving entrees, 25% of the meat/poultry entrees had nutrition labels, compared to 3.5% of pizzas, and none of the pasta entrees. Are we to conclude from this that frozen multi-serving pasta entrees are higher in fat than meat/poultry entrees? And is the difference in fat significant?

Second, the study compared only the fat content of labeled and unlabeled products. Yet consumers are interested in limiting their intake of other nutrients, also. It is not known whether a labeled product, lower in fat than an unlabeled product, is also lower in cholesterol, calories, and sodium. If so, are the differences significant?

The hypothesis that unlabeled products are higher in nutrients consumers wish to avoid does not seem to hold for sodium. Results from the 1986 FDA Food Label and Packaging Survey (FLAPS) (DSC, 1987) indicate that the average value for all sampled products declaring sodium increased from 1978 to 1982, as sodium labeling began to appear in relatively high sodium-containing categories such as cereals, baking mixes, prepared foods, soups, sandwich spreads, and meat extenders.

There is also some evidence that nutrition labeling decisions are being made on a corporate-wide basis and not on a product-by-product basis. Corporate-wide decision making would tend to reduce any value of a signal.

Thus, it is uncertain whether the mere presence of a label represents an appropriate signal regarding the nutrition quality of a product. However, if we accept for the sake of discussion that the absence of a label for a narrowly defined product may signal higher content of certain nutrients consumers wish to avoid, the next question to be addressed is whether consumers are aware of this potential signal, and is this signal likely to be used by high-risk groups? We address the question by considering evidence on the behavior and attitudes of this group.

It seems likely that high-risk consumers have difficulties processing nutrition label information. The Department of Education estimates that nearly 13 percent of American adults were functionally illiterate in 1982, defined as unable to match key words and phrases with fixed-choice alternatives on more than 20 of 26 questions of the Measure of Adult English Proficiency. Approximately a third of the functionally illiterate spoke

another language at home (Department of Education, 1986).

An FDA study (FDA, 1991b) on consumers' ability to use labels found that 9.5 percent of a sample selected were disqualified from the study by a literacy test. This supports the view that many high-risk consumers may not be able to process nutrition label information. Even among the literate, respondents with less education had lower accuracy, took longer to compare labels, and made more false positives (found differences between products where none existed).

Even if consumers with less education cannot process nutrition label information, and thus can only note a label's presence or absence, it is not certain that the presence of a nutrition label on a food product constitutes a useful signal of nutrition quality to them. Effective use of the signal would require the unsophisticated consumer to (i) be aware of the diet/health link, (ii) take action designed to improve health through diet.

Information on the characteristics of this high-risk population, however, raises doubt about the usefulness of the label signal in their purchasing decisions. Although consumers with less education more frequently report being told they have high or borderline cholesterol levels and high blood pressure, they are also less aware of and less knowledgeable about diet-disease relationships than other consumers. They are more likely to agree with the statement "What I eat won't make that much difference in my chances of getting heart disease" (FDA, 1991a), probably because they feel chronic diseases result from heredity and fate, and thus, are outside their personal control (DHHS, in press). Individuals with lower educational levels and lower incomes are less likely to follow practices to improve their health. Blacks report fewer habits intended to improve health than whites (DHHS, in press).

These findings suggest that the label/no-label signal is not likely to be a major benefit to the lower income, less educated consumers.

What about the value of the label as a signal to the average consumer? Focus group discussions conducted for FSIS by the Research Triangle Institute indicate that consumers think the labeled product is nutritionally "better." The question remains of whether the existence of the label is used as a signal to purchase. The only known study—conducted over 20 years ago—that has addressed this question directly attempted to determine the effect of the presence of a nutrition label on brand market shares (Yankelovitch, 1971). The result of this experiment indicated the existence of two "quality" signals—the leading brand and the presence of a nutrition label. When the leading brand was unlabeled, it maintained its market share in competition with a labeled brand. On the other hand, when unlabeled second or third ranking brands competed with a labeled leading brand, and the former lost market share. Thus, the experiment suggests that factors other than nutrition labels are important, and that reliance on the label signaling effect might lead to mixed results. It should be noted, however, that the study was a simulation of a shopping situation, not an actual market test, and that consumers might behave differently in a real shopping trip, when faced with both a budget and a time constraint.

In real shopping situations, unless consumers are actively seeking comparative nutrition information, they may simply ignore it because they do not consider the necessary proceeding effort worthwhile (Chaffee and McLeod, 1973 and Haines, 1974, as cited in Muller, 1985). Further, because of habitual buying and brand loyalty, consumers are not likely to change their purchasing behavior (i.e., use the label signal effect) unless they are convinced that the labeled brand is significantly better than the unlabeled brand (Muller, 1985).

Balanced against the potential benefits of the signal effect, if it exists, are the benefits consumers might derive from mandatory nutrition labels on all processed meat and poultry products. In a study conducted by Opinion Research Corporation for the National Food Processors Association (1990), over 80 percent of the consumers surveyed reported reading the nutrition information on the first purchase of a product, and were heavily influenced in their purchase decisions by nutrition information. These would be the primary beneficiaries of mandatory nutrition labeling.

In addition to the direct benefits to the consumers who use the information on the nutrition labels, there are likely to be indirect benefits to society as a group. These indirect benefits result from the reformulation which is likely to occur when manufacturers have to actually list on the label the nutrition composition of their products (Padberg and Caswell, 1990). Only a small proportion of consumers—or a consumer advocacy group—need be aware of the nutrition profiles of these foods to exert pressure on manufacturers to improve their products. Thus, under mandatory nutrition labeling, even unaware consumers will benefit from the improved, reformulated products.

Contrast the potential beneficiaries of mandatory nutrition labeling with the potential beneficiaries of the signal effect. This latter group would be primarily those who rarely or never read labels when first purchasing a product but who are influenced in their purchase decisions by nutrition information. This group is estimated to be less than 10 percent of consumers (calculated from Opinion Research Corporation, 1990, page 9).

III. Extent of Nutrition Labeling Under Voluntary Alternatives

A. Introduction

In the original PRIA, FSIS requested early comment on the expected percent of meat and poultry products with nutrition labeling under different voluntary labeling alternatives. Presumably, there are many factors that determine the current level of voluntary nutrition labeling. Many factors would affect the level of nutrition labeling if USDA implemented a voluntary program in which the labeling format was consistent with regulations that FDA has proposed to implement the Nutrition Labeling and Education Act (NLEA), the second option from the preliminary analysis. For example, it has been suggested that voluntary participation will increase because firms that produce both USDA and FDA-regulated products will add nutrition labeling to all their products when the FDA rules become final.

This analysis focuses on required analytical costs, which are an important, if not the only, determinant of the level of voluntary labeling. This section addresses the issue of how required nutrient analyses either have or would affect the level of voluntary nutrition labeling.

The preliminary analysis estimated that there are approximately 520,000 labels for processed meat and poultry products and that approximately 40 percent (208,000 labels) currently have some level of nutrition labeling. The 520,000 labels are used on an estimated 338,000 products. Assuming that 40 percent of the products have nutrition labeling, an estimated 135,200 products are currently analyzed for their nutrient content. (USDA is aware that firms also analyze non-labeled products and make such nutrient information available to consumers upon request.)

The preliminary analysis was based on estimates of the number of products (unique formulations) and labels that apply to retail sales of consumer-sized

packages. The proposed rule would not require modification of labels on products intended for hotels, restaurants, and institutions (HRI), but would require that nutrition information accompany the product. In cases where an HRI product has a retail counterpart, the nutrition information would already be available and incremental costs for institutional products would be minimal. In cases where an institutional product is a unique or special formulation there would be separate analytical costs to generate nutrition information for these products. The preliminary cost estimates did not include such costs. On the other hand, the cost estimates assumed that all establishments that conduct processing operations produce an "average" number of processed products for retail sale. FSIS knows there are establishments that produce only institutional products, fresh products or products for further processing in other establishments. Building preliminary cost estimates on the total number of establishments has, therefore, overestimated costs. But excluding testing for unique institutional products underestimated costs. FSIS believes that these two factors tend to balance each other.

The following analysis examines the 20-year costs of nutrient analysis for 135,200 products under the current system and under a voluntary program of labels required to be consistent with the FDA proposal. The analysis concludes that analytical costs are not expected to be substantially lower even after current testing requirements are removed.

B. Current Analytical Costs

Under existing procedures, nutrition labels are approved in conjunction with the Nutrition Labeling Verification (NLV) program. Under the current program, to obtain approval of a nutrition label, firms must submit the results from three separate analyses. After approval they must analyze the product each quarter during the first year and annually thereafter, assuming that all test results are consistent with the approved nutrient content. Thus, over a 20-year period, a product remaining in compliance would be analyzed 26 times (three plus four plus nineteen).

Under the current program firms have two options for format and style. They can use the format and style provided by FDA regulations (21 CFR 101.9) or they can use an abbreviated format that includes the number of calories and the number of grams of protein, carbohydrates, and fat in a specified serving of the product. Analytical costs are substantially lower for the abbreviated format.

To estimate current analytical costs, FSIS examined a sample of nutrition labels presented for approval in late 1991. The findings, presented in Table 1 show that approximately two-thirds of the sampled labels used the abbreviated format and that many firms now add cholesterol and/or sodium to the abbreviated format.

TABLE 1.—CONTENT OF EXISTING NUTRITION LABELS

Type of format	Nutritional information on labels	
	(labels w/ info)	(percent)
Abbreviated Format:		
Fat, Protein, Carbohydrates and Calories	148	100.0
Cholesterol	63	42.6
Sodium	74	50.0
Subtotal Abbrev. Format	148	100.0/67/6
Full Format:		
Vitamin A and C	71	100.0
Cholesterol	56	78.9
Saturated Fat and Calories From Fat	32	45.1
Sodium, Iron, Calcium	28	39.04
Niacin, Thiamine and Riboflavin	28	39.4
Dietary Fiber	8	11.3
Subtotal, Full Format	71	100.0/32.4
Total, All Formats	219	N/A/100.0

A weighted average analytical cost of $167 for the abbreviated format was estimated using the following cost estimates and frequencies from Table 1.

TABLE 2.—ESTIMATED TESTING COSTS: ABBREVIATED FORMAT

	Cost per test	Proportion of labels w/info	Weighted cost of test
Fat, Protein, Carbohydrates and Calories	$119	1.0	$119
Cholesterol	86	0.426	37
Sodium	22	0.5	11
Total Cost, Abbrev. Format	N/A	N/A	167

Using the average cost estimate of $167, the current 20-year, not discounted costs for a product using an abbreviated format would be $4,342 ($167 times 26).

A weighted average cost for the current full format was estimated using the following average costs and frequencies from Table 1.

TABLE 3.—ESTIMATED TESTING COSTS: FULL FORMAT

Test	Cost per test	Proportion of labels w/info	Weighted cost of test
Fat, protein, carbohydrates and calories	$119	1.0	$119
Cholesterol	86	0.769	68
Saturated Fat and Calories from Fat	82	0.451	37
Vitamin A and Vitamin C	110	1.0	110
Dietary Fiber	92	0.113	10
Thiamin, Riboflavin and Niacin (FDA, 1991C)	135	0.394	53
Sodium, Iron and Calcium	55	0.394	22
Total Cost Full Format	N/A	N/A	419

Using frequencies from Table 1 with the above costs results in an estimated weighted average cost of $419 per sample. Thus, 26 analyses for an average full format product would cost almost $11,000. The estimated current not discounted cost of 26 analyses for 135,200 products would be $874 million using an average weighted cost of $249 per analysis ($167 (.676)+$419 (.324)).

The above estimates could be viewed as the analytical costs associated with the NLV program. These costs raise two questions for comment. First, would firms test less if the NLV requirements were removed? Second, would removing the existing requirements lead to an increase in nutrition labeling, i.e., are the existing costs the reason that some firms do not particpate in the existing voluntary program?

C. Impact of a Revised Voluntary Program

The proposed rule does not specify any minimum testing requirement. The preliminary analysis was based on an assumption of one intial test for each product and 10 additional tests over a 20-year period. Thus, each product would be tested 11 times at an average cost of $368. The total costs, not discounted to present value, would be $4,048 per product. Thus, the projected 20-year costs under the 11 test assumption would be approximately the same as the existing NLV costs for the abbreviated format. If one accepts the 11 test scenario as a reasonable minimum amount of testing, then it would be difficult to argue that there would be any change in participation under a voluntary program with the proposed new format. Firms now using the full format would be able to reduce

their costs considerably, but the threshold cost of entering the program would remain about the same.

USDA does not have any information to answer the question of whether there would be more nutrition labeling today if the NLV program had not existed. Analytical costs are not the only issue. Comments received prior to the proposal indicate that some firms believe that their customers have little or no desire for nutrition information on their labels, especially if it is going to result in higher retail prices.

D. Comments on Preliminary Analysis

Some early comments received since publication of the proposed rule and PRIA on November 27, 1991 have suggested the USDA's estimates for laboratory analysis costs are extremely low. The analytical costs (except for thiamin, riboflavin and niacin) used for the above estimates are based on data the Research Triangle Institute collected from seven independent laboratories. It is recognized that these cost estimates are averages and the costs incurred by individual companies may vary widely. The averages are, however, consistent with other sources. For example, the cost estimates are consistent with data used in FDA's regulatory analysis which was based on pricing schedules from five independent testing laboratories. The FDA analysis used $595 for a complete analysis (including sugars). The preliminary FSIS analysis used $506 as a cost for the 13 nutrients/components most likely to be found in meat and poultry products (cost of sugar analysis not included).

E. Assessment of Recipe Analysis

The cost analysis and discussion thus far has been based on an assumption that nutrition labels will have to be supported by the results from laboratory analysis of product samples. Nutrient profiles can also be determined by "recipe analysis". Recipe analyses are accomplished by comparing a list of ingredients (formulation) with existing data bases that contain data on the nutrient content of the various ingredients.

USDA is continuing to review the potential for supporting nutrition labels with recipe analyses. Since the nutrient content of all products will vary from sample to sample, the key question is how a recipe analysis compares with the average result from two or three laboratory analyses as an estimate for average nutrient content. If recipe analyses can replace laboratory analyses for many products, then the overall costs of supporting nutrition labels can be dramatically reduced. A recipe analysis is a one-time expense that may be repeated over time as data bases are improved and methodology changes.

IV. Costs Associated With Prior Label Approval

A. Introduction

In the PRIA, FSIS also asked for early comments on the costs associated with the prior label approval process. Specifically, FSIS asked whether data exist on the length of time it takes to bring a product to market relative to a system where prior approval is not required.

As indicated in the preliminary analysis, an estimated 520,000 labels would have to be revised in order to comply with the proposed rule. This estimate assumes that all existing labels would be revised and all existing products would be continued. The Agency currently has established 12 positions at headquarters to review and approve labels. Under current procedures, this staff has been able to handle approximately 140,000 to 150,000 applications per year. The proposal thus raises an obvious question of how FSIS intends to handle the process of approving nutrition labels under the proposed rule. Since the proposal was published in November 1991, FSIS has issued a background publication on efforts to modernize the label review process. That publication is included as appendix A to this supplemental analysis.

Another change that simplifies the approval process is the decision not to request support data as part of the label application. This analysis includes a summary of existing cost data related to the approval process and a discussion of the broader regulatory policy issue raised by the presence of the prior label approval process.

B. Cost Data

The label approval process begins with an application that includes a sketch or final label, a completed form requesting approval, and any supplementary information included to support the accuracy of claims made by the label. The applications can be mailed to FSIS or hand carried by employees of independent firms referred to as expediters. Today, an estimated 85 percent of label applications are handled by expediters. Although fees are up to the discretion of each firm, the average fee for a label which is approved with no delay is $10. This covers an estimated 80 percent of the labels.

When labels require additional inquiry or additional time, expediters generally charge an estimated $50 per hour. Assuming that 20 percent of the labels average one hour each, the expediter costs for 520,000 labels would be $4.16 million for 80 percent at $10 each and $5.2 million for 20 percent at $50 each. There would also be some cost associated with forwarding and retrieving the label application.

The second type of cost is company time required to prepare and review the application. Since meat and poultry firms have incorporated obtaining label approval as part of normal operating procedures, the label appliation costs would presumably be incorporated in the estimates for administrative costs that were included in the preliminary analysis. The preliminary analysis estimated the following average administrative costs of bringing labels into compliance under the proposed rule, assuming a one-year period between promulgation of a final rule and the effective date:

Small Companies	$9,293
Medium Companies	$4,554
Large Companies	$86,333

Although not quantified, interviewed companies maintained that administrative costs would be higher for shorter compliance periods.

One trade association has provided some preliminary survey data that separates the prior label approval costs from other administrative costs. A small sample of processors estimate they devote 29.0 person hours per product per year to the prior label approval process. Larger companies require fewer person hours per product, while smaller companies require more time. The same processors estimate their direct costs per product to complete the USDA prior label approval process are nearly $1,000. This figure includes costs for alternate label designs, fees to label expediters, travel expenses, etc. Clearly, the costs attributable to the proposed rule on nutrition labeling should be much lower than this. More complete data will be submitted to FSIS with further comments on nutrition labeling of meat and poultry products.

The third type of cost is related to any delay caused by the process. Because the process takes time, there could be a delay in getting a new product on the market. The companies responding to the trade association survey estimated that the time from the decision to market a new or modified product until actual market placement, for a company's FSIS regulated processed foods, averages over 28 weeks. The reported time from

the decision to market a new or modified product until actual market placement, for a company's FDA-regulated processed foods, averages nearly 18 weeks. The reported time differential factor for FSIS-regulated processed foods is 1.6. This factor largely reflects the additional time required for USDA's prior label approval system. The marketing practices for processed foods regulated by the two agencies are in most cases identical, except for prior label approval.

At the present time, the Department does not have sufficient data to estimate an accurate overall cost or benefit attributable to the prior label approval system. The Department has initiated a study of the costs and benefits of alternative options. There are factors that would affect the costs and benefits of different options, such as necessary changes in inspection activities. There are also benefits of the existing system in that some firms may now avoid the costs of maintaining their own expertise on labeling policies and regulations.

C. Broader Policy Implications

When a label application raises a complex or controversial labeling policy issue, it may take weeks to obtain an approval. In these cases, however, the delay is related to regulatory policy decision making and rarely to the fact that a prior approval process exists. Firms establishing new products in controversial areas may want an advanced regulatory review, with or without a label approval process.

Prior label approval is one of several Federal regulatory actions that tend to minimize decision making risk or limit liability for the private sector. There are similarities to the issuance of safety standards for consumer products and similarities to pre-market clearance for drugs. To the extent that the process improves compliance the process also provides public health benefits.

In the case of consumer products, firms may believe that compliance with a Federal safety standard is insurance against potential product liability lawsuits. The pre-market clearance for drugs is similar in that Federal approval would appear to limit private liability. The regulatory actions help assure a strategy of minimizing maximum regret. For labels, the maximum regret would be to develop a new product, invest in label and advertising and then have the product removed from the market because of something wrong with the formulation or the label. Prior label approval is not just a clearance for the label, it is also an assurance that the product complies with any applicable standards of identity, standards of composition, minimum meat content requirements and a variety of labeling policy decisions.

Requests for label approval may include a request for a new process or a new procedure and may involve the approval of a new piece of equipment. FSIS functions of label approval, equipment or blueprint approval, and processing regulations are all separate but interrelated extensions of the inplant inspection process. If label approval is contingent on another type of approval, delays in marketing a new product should not be attributed to the prior label approval process. Further comments should recognize that the term prior label approval is frequently used to include requests that involve new processes and new technology and to raise regulatory issues related to existing process requirements and product standards.

V. Other Impact Issues Raised

A. Introduction

This section addresses concerns expressed in some of the initial comments on the preliminary regulatory impact analysis. The purpose is to provide clarification and focus issues for additional comment. This discussion is not a comprehensive discussion of all comments received to date.

B. Impact on Small Business

Several commenters have mentioned the impact that nutrition labeling rules will have on small firms, especially those firms that produce relatively small quantities of many different products. The preliminary analysis provided estimates on the increased cost of production per pound to help illustrate the economic situation that small firms will face. Estimating impacts such as business closure was beyond the scope of the PRIA.

This is not an area where there is disagreement. The proposed rule would create difficulties for small businesses. USDA has been requesting comments on how to address or solve the problem. USDA has not provided a small business exemption. Without an exemption, USDA will continue to examine the issues of data bases, recipe analysis and implementation time as options for easing the burden on small business.

Two trade associations are collecting economic data on small businesses from their members. These findings support the assumption in the PRIA that the 3,376 State-inspected plants would be the smallest companies. One effort has assembled responses on annual sales from 49 State-inspected plants. Forty-eight of these plants had annual sales less than $5 million. Over 60 percent had annual sales below one million dollars. The 49 State plants averaged 40 products per plant. The PRIA was based on estimates of 43 active labels and 39 products per small plant. Fourteen State plants reported production of less than 20,000 pounds of their best selling product.

The early comments tend to support the analysis but suggest that many small companies would go out of business given the cost assumptions used in the PRIA. This is a serious issue. The final regulatory impact statement will reassess the cost estimates. It will also include analysis of alternative regulatory options including the possibility of small business exemptions.

C. Loss of Brand Names

A trade association pointed out that the PRIA failed to consider the loss of market share when a well established brand name is no longer permitted to be used. Such costs redistribute revenue among firms, if consumer expenditures on processed meat and poultry products are unchanged. Thus, they would not affect this aggregate analysis. Nevertheless, USDA recognizes that the costs could impose a burden on individual firms, a burden that should not be imposed capriciously.

USDA is aware that some of the descriptors defined by the proposal are currently part of product names. For each case there are three potential outcomes. These are:

(1) The product meets the descriptor definition and the product name can continue to be used without change.

(2) The product can be reformulated so that the product name meets the proposed definition.

(3) The product is unchanged but the name must be changed.

The overall impact will vary on a case-by-case basis. Some reformulated products will result in increases in market share, but other products will have less. However, consistent terminology serves the consumer and should bring market share more in line with consumer demands.

D. Market Changes

The PRIA requested comments on expected shifts in consumption patterns and changes in market shares of different foods. USDA has not received sufficient information to address these issues, although some firms will drop products such as specialty items to reduce costs. Another comment suggested that firms will discontinue

product lines that will no longer be allowed to bear descriptors about moderate reductions in unwanted nutrients.

E. Benefits Methodology

Comments have questioned the overall methodology used to estimate benefits. As is true for other health and safety regulations, it is usually easier to quantify costs than benefits. The benefits analysis is less objective and does depend on assumptions with greater uncertainty. Regulatory decisions always include a level of uncertainty. USDA believes that including the analysis will help stimulate more meaningful comments and thus facilitate the decision making process.

Some commenters have incorrectly concluded that the benefit estimates are based on a totally arbitrary assumption that there is a relationship between label changes and dietary modification. The benefits are based on extrapolations from measured dietary changes that resulted from shelf labeling conducted during the FDA-sponsored Special Dietary Alert program.

VI. Summary of Costs and Benefits

FSIS has proposed mandatory nutrition labeling for processed meat and poultry products, and voluntary nutrition labeling for raw, single-ingredient meat and poultry products. This analysis also considers the consequences, costs, and benefits that might be associated with a voluntary program for nutrition labeling, consistent with FDA's proposed regulations, under two sets of conditions. These alternatives are compared with the proposed rule.

FSIS proposes to use laboratory testing to determine whether labels are consistent with the nutrient content of foods. Such testing might be an incentive for manufacturers to conduct laboratory analyses on their products. The alternative is referred to as "voluntary program with laboratory tests". This is equivalent to option 2 in the original regulatory impact analysis (voluntary program consistent with FDA), and is presented here with additional explanations and clarifications.

The second set of conditions assumes manufacturers base their nutrition labeling on "recipe analysis", using approved data bases. This alternative is referred to as "voluntary program with recipe analysis".

In addition, this section analyzes an alternative of mandatory nutrition labeling for processed meat and poultry products, with a voluntary program for raw, single-ingredient, meat and poultry products, assuming use of recipe analysis for support of the nutrition data presented on the label. This alternative is referred to as "mandatory/voluntary program with recipe analysis."

Lastly, this section introduces a new option, the proposed voluntary/mandatory option without prior label approval. The issue of regulatory and/or statutory changes that could be necessary to modify existing prior label approval procedures is not addressed.

A summary of the expected advantages and disadvantages of each alternative follows, and benefits and costs are compared to the proposed voluntary/mandatory option.

1. Voluntary Program With Laboratory Tests

In the original PRIA, it was assumed that compliance with the new nutrition label requirements (which basically requires information on a larger number of nutrients) would increase costs to firms. This was expected to reduce the proportion of products exhibiting nutrition labeling on a voluntary basis to below the estimated current 40 percent.

The original assumption and the accompanying analysis changes little. As described above, it is estimated that approximately two-thirds of the meat and poultry products which currently provide voluntary nutrition labeling use the abbreviated format, which requires information only on calories, fat, carbohydrates, and protein. Some also included information on cholesterol and/or sodium to the abbreviated format. Average analytical costs are estimated to be $167 per test per product. Considering current requirements under the Nutrition Labeling Verification (NLV) program, which requires 26 analyses over a period of 20 years, it is estimated that the costs, not discounted, for each product using an abbreviated format would be $4,342. For products using the full format, the estimated cost, not discounted, of 26 analyses over 20 years would be close to $11,000 per product.

Under the voluntary program with laboratory tests, there are no specified number of analyses that must be completed. Rather, manufacturers of processed meat and poultry products are required only to maintain records and make them available upon request. It is assumed that, in order to maintain appropriate records, manufacturers will conduct one initial analytical test for each product, and update the analysis once every two years. Under this conservation assumption, each product would be tested on average of 11 times over a period of 20 years. However, the conditions permitting use of the abbreviated format would be more stringent, and nearly all labels would have to provide information for at least the following ten nutrient/components: calories, fat, carbohydrates, protein, sodium, saturated fat, cholesterol, iron, calcium, and calories from fat. Some products would also have to be tested for one or more of the following: Vitamin A, Vitamin C, and fiber. Using a weighted-average cost of $368 as estimated in the PRIA, the estimated cost, not discounted, of 11 analyses over 20 years would be $4,048.

If one accepts the 11 test scenario as a reasonable minimum amount of testing, products now using the full format would see their analytical costs considerably reduced under the proposed new format. However, nearly two-thirds of products currently carrying voluntary nutrition labeling are estimated to use the abbreviated format. For these products, the difference in analytical costs is smaller, and may not even be significant. Moreover, these comparisons are based on the assumption that manufacturers will conduct only one initial test, and will retest only once every two years. Should manufacturers feel it is necessary to conduct even one more additional analysis, estimated analytical costs under the proposed new program would become greater than for the abreviated format under the current program.

We conclude that the threshold cost of entering the program would remain about the same. If analytical costs were the only factor in the manufacturer's decision of whether to use a voluntary nutrition label, this analysis suggests that there would be few new entrants into the program. These would be unlikely to significantly exceed the current 40 percent of products carrying voluntary nutrition labeling.

Total costs under a voluntary labeling program, with laboratory tests, with an expected 40 percent of products participating in the program, include administrative costs, market testing costs, printing costs, and inventory transition costs, in addition to analytical costs. Since no increase in the proportion of products participating in the program from the current 40 percent is expected, total costs are estimated to be approximately 40 percent of the total cost estimated under the voluntary/mandatory program.

Benefits are expected to be minimal, since no increase in the proportion of labeled products is expected. Benefits would be associated only with the increase in nutrition information made available on the labels of labeled

products. These benefits are estimated to represent 10 percent of the total benefits under the voluntary/mandatory program.

PRO

- Products would carry consistent nutrition information, regardless of whether they are regulated by USDA or FDA, thereby reinforcing information received by consumers and improving ability to compare.
- More nutrition information would be available to consumers on those products that continue to be labeled.
- Firms, including small businesses, would have the option to avoid labeling costs by choosing not to label their products.

CON

- Under this voluntary program, many meat and poultry products would remain unlabeled. It seems unlikely that more than 40 percent of meat and poultry products would carry voluntary nutrition labeling. With incomplete information, consumers will continue to make choices they might not make under full information.
- Consumers could lose confidence in USDA's interest in providing nutrition information.
- Estimated quantifiable benefits are smaller than the costs of this option.

2. Voluntary Program With Recipe Analysis

Under this alternative, manufacturers would support the nutrition content on their labels by recipe analysis. Such an approach depends on the adequacy of existing data bases of the nutrient contents of foods, such as the National Nutrient Data Bank maintained by the Human Nutrition Information Service of USDA. Current data bases are not complete so much depends on how quickly adequate data bases become available.

If recipe analysis can replace laboratory analyses for many products, the overall costs of supporting nutrition labels can be dramatically reduced. One example of such an approach is available; the National Restaurant Association provides a computerized analysis of recipes to members at $10 a recipe (National Academy of Science, 1990, p. 147).

A potential problem with recipe analysis is the wide variation in the nutrient content of foods due to two types of variations. First, variations in production conditions, such as soils, weather, etc. for crops and feed, breed, etc. for animal products, are known to be responsible for wide variations in the nutrient content of foods. Nutrient content in data bases likely reflect averages of a large number of samples. Second, the variation in the amounts of ingredients in a recipe may also lead to wide variations in the nutrient content of the particular food product. However, these problems may be manageable if manufacturers are cautious in their estimated nutrient content on the label, and if data bases constructed to account for variability become available. Without further information, USDA must continue to assume that there will be some reduction in benefits resulting from the use of recipe analysis.

Unfortunately, there are no estimates available on the proportion of products that would use recipe analysis to support their nutrition label. Some manufacturers might still choose to perform analytical tests on their products for their own protection and liability. Others might decide to conduct analytical tests since it is often difficult to determine the exact effect that processing will have on the raw ingredients. No estimates are available from FDA-regulated food products, either, since FDA has traditionally emphasized that they would check for compliance using analytical methods. It is assumed that smaller companies are more likely to opt for recipe analysis, whereas larger companies will continue to conduct analytical tests.

Since recipe analysis is expected to be so much cheaper than analytical testing, one would expect to see new products entering the labeling program. However, once again, it should be emphasized that analytical costs are not the only factor involved in a manufacturer's decision of whether to include nutrition information on a product's label. Therefore under a voluntary program with recipe analysis, more than the current 40 percent but less than 100 percent of all processed meat and poultry products will have nutrition labeling. For this analysis, we assume that between 50 and 70 percent of the products will have voluntary nutrition labeling. We further assume that all of the new entrants will use recipe analysis, whereas products already in the program will continue to use analytical tests to determine the nutrient composition of the food product.

Total costs of labeling will include administrative costs, market testing costs, printing costs, and inventory transition costs, in addition to analytical costs. Analytical costs represent close to half of total manufacturers' costs in the analysis detailed in the PRIA. Therefore the analysis assumes that, for the products using recipe analysis, total costs are reduced to one-half of the total costs using analytical tests.

If each 10-percentage-point increase in the proportion of labeled products above the current 40 percent is associated with a health benefit of $0.3 billion, benefits from a voluntary program using recipe analysis would range from $0.5 to $1.1 billion. However, this may overestimate the benefits. If recipe analyses prove less accurate, there could be a reduction is benefits.

PRO

- The proportion of products providing voluntary nutrition labeling is expected to be greater than the current 40 percent.
- Products would carry consistent nutrition information, regardless of whether they are regulated by USDA or FDA, thereby reinforcing information received by consumers and improving ability to compare.
- More nutrition information would be available to consumers on those products that continue to be labeled.
- Firms, including small businesses, would have the option to avoid labeling costs by choosing not to label their product.
- Firms would face lower costs under recipe analysis compared with laboratory tests.

CON

- Under this voluntary program, not all processed meat and poultry products are likely to provide nutrition labeling on a voluntary basis. A number of meat and poultry products will remain unlabeled.
- It is possible that products containing large amounts of nutrients consumers wish to avoid will not provide nutrition labeling, leading consumers to make choices they might not make under a complete labeling program.
- Consumers could lose confidence in USDA's interest in providing nutrition information.
- There would be initial costs to establish reliable data bases.
- Estimated quantifiable benefits would be reduced, compared with laboratory testing, since recipe analyses are probably less accurate than laboratory testing.

3. Voluntary/Mandatory Program With Receipe Analysis

Costs of compliance are expected to be much lower using recipe analysis than using analytical tests. If feasible, this would present less of a financial burden for smaller businesses.

Since the program would remain voluntary for raw, single-ingredient meat and poultry products, and

mandatory for all processed meat and poultry products, 100 percent of all processed meat and poultry products would provide nutrition labeling, and the benefits would remain the same as under the proposed voluntary/mandatory program.

Costs incurred by the manufacturers, however, should be greatly reduced, due to the lower cost of using recipe analysis compared to doing analytical tests for nutrient composition. Once again, however, it is difficult to estimate costs, since there are no estimates as to what proportion of the products bearing nutrition labeling would use recipe analysis. Some manufacturers might still choose to use analytical tests on their products to support the nutrition information on the product's label, either for their own protection and liability, or because it is sometimes difficult to determine the exact effect that processing will have on the raw ingredients. It does not seem reasonable, under a mandatory nutrition labeling program, that all new entrants will choose to use recipe analysis. Therefore, for this option, it is assumed that half of the new entrants will use recipe analysis to support their nutrition label, and that total costs for these products are then half of the costs incurred by products supported by analytical tests. The remaining half of new entrants will choose to use analytical tests.

PRO

- Consumers would face uniform labels on all processed food products. Widespread, uniform labels would allow motivated consumers to reduce excess consumption of nutrients associated with coronary heart disease, high blood pressure, and several forms of cancer, and consequently avoid early deaths from these diseases.
- Mandatory labeling would probably lead to product reformulation, with additional benefits even among consumers who might not read labels.
- Lower costs to manufacturers, compared with laboratory testing, would reduce the financial burden imposed on manufacturers, and reduce the costs that might be passed on to consumers.
- Estimated quantifiable benefits exceed costs.

CON

- All manufacturers would face the costs of relabeling their products.
- The large number of new labels required under this option would make prior label approval severely restraining, unless it were significantly streamlined.
- There would be initial costs to establish reliable data bases.
- Benefits would be reduced, compared with laboratory testing, because recipe analysis may be less accurate.

4. Voluntary/Mandatory Labeling Without Prior Approval

This option analyzes a voluntary/mandatory labeling program with laboratory testing, as proposed. However, in order to reduce manufacturers' compliance costs, prior label approval is eliminated. Removal of prior label approval would reduce the Department's administrative costs of maintaining a full staff (currently of 12 people) for approving all labels, although this would be offset by higher verification and analytical costs related to the Department's compliance program.

Prior label approval may represent a bottleneck at the beginning of the program, when in excess of 500,000 labels for all processed meat and poultry products would be coming in at the same time. However, these costs need to be compared with the costs involved under the alternative option of no prior approval. For those labels found to be in non-compliance, manufacturers would face the loss of costs involved in label and advertising, plus removal of the product from the market, and perhaps loss of consumer confidence.

PRO

- Removal of prior label approval would remove the bottleneck at the beginning of the program, when a large number of labels will be changing at once.
- Removal of prior label approval reduces manufacturers' administrative costs.
- Removal of prior label approval gives manufacturers more flexibility in deciding how to comply with labeling regulations.

CON

- Removal of prior label approval eliminates the assurance that the product complies with all applicable standards of identity, standards of composition, minimum meat content requirements, and a variety of labeling policy decisions. FSIS statutes may require some change in inspection activities at the plant level to replace the prior label approval system.
- Removal of prior label approval places manufacturers at risk of significant loss if labels are found in non-compliance.
- Removal of prior label approval might affect the level of compliance. Inaccurate labels could reduce health benefits.

The final discussion of benefits and costs is based on information summarized in the following table:

BENEFITS AND COSTS OF ALTERNATIVE OPTIONS

	Voluntary labeling		Voluntary/mandatory labeling		
	Laboratory testing	Recipe analysis	Recipe analysis	No Prior approval [1]	Proposed regulation
Percent of Processed Products Labeled on Final Implementation Date	40	50–70	100	100	100
Manufacturers' Costs (billion dollars)	[2] .5	[3] .6–.7	[4] 1.1		1.3
Data base development costs for recipe analysis (billion dollars)		.1–.2	.1–.2		
Health Benefits (billion dollars)	[5] .2	[6] .47–1.0	[7] 1.8		2.0
Benefit/Cost Ratio	.40	.59–1.25	1.38–1.50		1.54

[1] No adjustment has been made at this time in costs and benefits of this option compared with the proposed regulation because the Department has initiated a study of the costs and benefits of prior label approval.

[2] (.40*1.3)

[3] [(.40*1.3)+(.10*.65)], [(.40*1.3)+(.30*.65)] (assumes 10–30 percent of these products use recipe analysis).

[4] (.40*1.3)+(.30*1.3)+(.30*.65) (assumes 30 percent of these products use recipe analysis).

[5] (.10*2.0) (assumes minimal health benefits equal 10 percent of estimated benefits from proposed rule).

[6] 0.2+[(1.0*0.3)−(.10*0.3)], 0.2+[(3.0*0.3)−(.10*0.9)] (assumes health benefits are reduced due to higher inaccuracy of labels using recipe analysis).

[7] [2.0−(.1*2.0)] (assumes health benefits under recipe analysis are 10 percent lower than estimates under proposed rule due to higher inaccuracy of labels using recipe analysis).

References

Chaffee, S.H., and J.M. McLeod. "Consumer Decisions and Information Use." In Consumer Behavior: Theoretical Sources, S. Ward and T.S. Robertson, eds. Englewood Cliffs, NJ: Prentice-Hall, Inc, 1973 (cited in Muller, 1985).

DCS. Sodium content of the retail food supply: 1986. Division of Consumer Studies, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Washington, DC, July 1987.

DHHS/PHS/ODPHP. Promoting Healthy Diets and Active Lifestyles to Lower-SES Adults. Market Research for Public Education. Office of Disease Prevention and Health Promotion, Department of Health and Human Services, Washington, DC (in press).

FDA. "Summary of Research on Health and Diet Attitudes and Knowledge and Use of Food Labels". Center For Food Safety and Applied Nutrition, Division of Consumer Studies, July 1991a.

_____. "A Study of Nutrition Label Formats: Performance and Preference." Center for Food Safety and Applied Nutrition, Division of Consumer Studies. July 1991b.

_____. Food Labeling, FR 56 No. 229, 60366, November 27, 1991c.

Haines, G.H. "A Prologue to Four Papers on Information Search." In Buyer/Consumer Information Processing, G.D. Hughes and M.L. Ray, eds. Chapel Hill: University of North Carolina Press, 1974 (cited in Muller, 1985).

Muller, T.E. "Structural Information Factors which Stimulate the Use of Nutrition Information: A Field Experiment." Journal of Marketing Research, 22 (May 1985): 143–157.

National Academy of Sciences, Institute of Medicine, Nutrition Labeling, National Academy Press, Washington, DC, 1990.

Opinon Research Corporation. "Food Labeling and Nutrition: What Americans Want". Survey conducted for the National Food Processors Association, Washington, DC 1990.

Padberg, D.I. and J.A. Caswell. "Toward a More Comprehensive Theory of Food Labeling." WP–19, Working Paper Series of NE–165 Private Strategies, Public Policies and Food System Performance, a Joint USDA Land Grant University Research Project, May 1990.

U.S. Dept of Education, Office of Educational Research and Improvement, Update on Adult Illiteracy, April 1986.

Yankelovich, Inc. "Nutrition Labeling: An Experiment to Determine the Effects of Nutrition Labeling on Food Purchases". Chain Store Age, Supermarkets Store edition, vol. 47, pp. 57–77. Jan. 1971.

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